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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/616,718	07/14/2000	Bert L. Vallee	11187-00001	5959	
22469	7590 08/28/2003	•			
	SCHNADER HARRISON SEGAL & LEWIS, LLP			EXAMINER	
1600 MARKET STREET SUITE 3600			DELACROIX MUIRHEI, CYBILLE		
PHILADELPH	IIA, PA 19103		ART UNIT PAPER NUMBER		
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		•	1614	,/	
			DATE MAILED: 08/28/2003	15	

Please find below and/or attached an Office communication concerning this application or proceeding.

,		Application No.	Applicant(s)
		09/616,718	VALLEE ET AL.
	Office Action Summary	Examiner	Art Unit
		Cybille Delacroix-Muirheid	1614
D 16	- The MAILING DATE of this communication a		1
THE I - External after - If the - If the - If ailu - Any r earne	ORTENED STATUTORY PERIOD FOR REP MAILING DATE OF THIS COMMUNICATION nsions of time may be available under the provisions of 37 CFR 1 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a re- period for reply is specified above, the maximum statutory perior re to reply within the set or extended period for reply will, by statu- eply received by the Office later than three months after the maili- ed patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be tirply within the statutory minimum of thirty (30) day d will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE and date of this communication, even if timely filed.	nely filed s will be considered timely. the mailing date of this communication.
1)⊠ —	Responsive to communication(s) filed on 17	<u>' April 2003</u> .	
2a) <u></u> □	This action is FINAL . 2b)⊠ T	his action is non-final.	
3) Dispositi	Since this application is in condition for allow closed in accordance with the practice under on of Claims	vance except for formal matters, pr r <i>Ex parte Quayle</i> , 1935 C.D. 11, 4	rosecution as to the merits is 153 O.G. 213.
4)⊠	Claim(s) 1-3,5,6 and 13-15 is/are pending in	the application.	
•	4a) Of the above claim(s) is/are withdra	awn from consideration.	
5)⊠	Claim(s) <u>1,2 and 13-15</u> is/are allowed.		
6)⊠	Claim(s) <u>3,5 and 6</u> is/are rejected.		
7)	Claim(s) is/are objected to.		
8)□	Claim(s) are subject to restriction and/o	or election requirement.	
Application	on Papers	·	
9)□ 1	he specification is objected to by the Examine	er.	
10) <u></u> ⊤	he drawing(s) filed on is/are: a)□ acce	epted or b) objected to by the Exar	miner.
_	Applicant may not request that any objection to the		
11)∐ T	he proposed drawing correction filed on		ved by the Examiner.
	If approved, corrected drawings are required in re		
	he oath or declaration is objected to by the Ex	xaminer.	
	nder 35 U.S.C. §§ 119 and 120		
	Acknowledgment is made of a claim for foreig	n priority under 35 U.S.C. § 119(a))-(d) or (f).
a)[_	☐ All b)☐ Some * c)☐ None of:		
•	 Certified copies of the priority document 	ts have been received.	
2	Certified copies of the priority document	ts have been received in Application	on No
	B. Copies of the certified copies of the prio application from the International Buse the attached detailed Office action for a list	reau (PCT Rule 17 2(a))	
	knowledgment is made of a claim for domesti		
a)	☐ The translation of the foreign language procknowledgment is made of a claim for domest	ovisional application has been rece	eived.
Notice Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Informal Page	(PTO-413) Paper No(s) atent Application (PTO-152)
Patent and Trac OL-326 (Rev	. 04.04)	ction Summary	Part of Paper No. 15

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Detailed Action

- 1. Claims 3, 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallee et al., 5,204,369 or Vallee et al., 5,624,910.
- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to the request for continued examination under 37 CFR 1.114 and the accompanying amendment received April 17, 2003.

No claims are cancelled. New claims 13-15 are added. Claims 1-3, 5-6 and 13-15 are currently pending.

The previous rejection of claims 3, 5 under 35 USC 103(a) over Keung et al., maintained in the office action mailed Nov. 20, 2002 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim objection set forth in paragraph 3 of the office action mailed Nov. 20, 2002 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, paragraph 2, set forth in paragraph 4 of the office action mailed Nov. 20, 2002 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

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The previous double patenting rejection maintained in the office action mailed Nov. 20, 2002 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous rejection of claims 3, 5-6 under 35 USC 103(a) set forth in paragraphs 5-7 of the office action mailed Nov. 20, 2002 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Nov. 20, 2002 with the following additional comment:

It is essentially Applicant's position that Vallee '369 and '910 do not disclose or fairly suggest therapeutically reducing alcohol consumption by administering the claimed compound in an effective amount "to increase the concentration of an aldehyde formed during catabolism of a neurotransmitter." The '369 and '910 patents are primarily concerned with identifying ALDH-I inhibitory compounds and compositions. Therefore, these patents modify alcohol consumption via inhibition of ALDH-I.

Moreover, the patents are silent with respect to increasing the concentration of an aldehyde formed during catabolism of a neurotransmitter. On the other hand, Applicant has discovered a mechanistic basis for reducing alcohol consumption, that is to say that Applicant has discovered that the claimed compounds have the property of increasing the concentration of aldehydes formed during catabolism of a neurotransmitter.

Said arguments have been considered but are not found to be persuasive.

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Concerning Applicant's argument that the patents do not disclose a method of reducing alcohol consumption by administering the claimed compound in an effective amount "to increase the concentration of an aldehyde formed during catabolism of a neurotransmitter", the Examiner respectfully submits that Applicant is arguing (as well as claiming) the effective amounts functionally, i.e. an effective amount to increase the concentration of an aldehyde formed during catabolism of a neurotransmitter. However, upon reference to the specification, the Examiner is unable to find any disclosure of effective amounts. Additionally, Applicant has not clearly argued how this amount desired by Applicant is not disclosed or is distinguished over the amount disclosed in the method of the prior art. Applicant has not specifically argued, on the record, how the claimed amounts of compound used in the claimed alcohol consumption reduction method differ from the amount of identical compound used in the alcohol consumption or alcohol abuse treatment methods in the prior art. Absent such arguments, the Examiner respectfully maintains that the claimed increase in aldehyde concentration would have been obvious in the method of the prior art.

Next, with respect to the discovery of the compound's ability to increase the concentration of aldehyde formed during catabolism of a neurotransmitter, the Examiner respectfully submits that the discovery of an unexpected property of a compound disclosed in the prior art does not necessarily render the claimed method unobvious since this property may be inherent in the prior art. Please see In re Best, 195 USPQ 430; In re Swinehart, 169 USPQ 226 ("a newly discovered property does not necessarily mean the product is unobvious, since this property may be inherent in the

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prior art."). Furthermore, the Examiner respectfully submits that Applicant's argument addresses the discovery of an unexpected <u>property</u> of a compound already disclosed by the prior art. It does not serve to distinguish the claimed <u>method</u> from the <u>method</u> disclosed by Vallee '369 and '910.

It is for these reasons that the rejection is respectfully maintained.

Allowable Subject Matter

Claims 1, 2 and 13-15 are free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed methods.

Conclusion

Claims 3, 5-6 are rejected.

Claims 1, 2, 13-15 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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CDM,

August 24, 2003

Cybille Delacroix-Muirheid Patent Examiner Group 1600